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10/027,418	12/19/2001	Himanshu Patel	018489-002510US	2779

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT PAPER NUMBER

3731

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,418

Applicant(s)

PATEL ET AL.

Examiner

Bradford C Pantuck

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 24-31 and 61 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-38 and 63-68 is/are allowed.
- 6) ☒ Claim(s) 1-23, 39, 41, 44-60, and 62 is/are rejected.
- 7) ☒ Claim(s) 40, 42 and 43 is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/19/2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-23, 32-60, and 62-68, drawn to a catheter and method of using it, classified in class 606, subclass 159.
- II. Claims 24-31, drawn to a catheter with a cam and a drive shaft, classified in class 606, subclass 159.
- III. Claim 61, drawn to a catheter kit, classified in class 606, subclass 159.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because not all of the particulars the catheter system of Group I are required by claims 24-31. For example, the combination does not require a flexible body and rigid housing. The subcombination has separate utility such as cutting cancerous lesions from the inside of the body.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

2. Inventions III and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination claims the catheter very broadly. The subcombination has separate utility such as cutting cancerous lesions from the inside of the body.

Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group II, restriction for examination purposes as indicated is proper.

3. Inventions III and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination claims the catheter very broadly. The subcombination has separate utility such as cutting cancerous lesions from the inside of the body.

Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Craig P. Wong on December 16, 2003 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-23, 32-60, and 62-68. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-31 and 61 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

4. The title of the invention is not descriptive. A new title is required that is clearly *indicative of the invention to which the claims are directed*. Specifically, Applicant should reference the fact that the catheter is deflectable, rotatable or other similar language.

Claim Objections

5. Claim 21 is objected to because of the following informality: in line 3, the word lumen should be made plural.
6. Claim 53 is objected to because of the following informality: in line 1, it is unclear what is meant by "parting off." It is assumed that this is a typo. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the tissue debulking assembly can (assumedly by itself ?) move a "longitudinal axis of the debulking assembly."
8. Claim 49 recites the limitation "the material" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,620,447 to Smith et al. Regarding Claims 1 and 2, Smith discloses a catheter having all of the claimed features. Smith's catheter has a flexible body and a rigid housing (74) [Column 7, lines 61-67] rotatably coupled to the distal end of the flexible body (14) [Column 5, lines 53-60]. The housing has a window (13). Smith's assembly also includes a tissue debulking assembly, a rotatable cutter (15), disposed within the housing [Column 5, lines 53-60]. While the distal part of the instrument is deflected (see Figures 1 and 2), the tissue debulking assembly is exposed through the window (13). Figure 2 shows, quite clearly, the cutter (13) protruding from the window.

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10. Claims 1-8, 10, 14-23, 49-60, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,979,951 to Simpson. Regarding Claims 1, 5, 14, and 17, and with reference to Figures 1 and 2, Simpson discloses a catheter with a flexible body (36). Rotatably coupled [see explanation just below] to the distal end of the flexible body (36) is a rigid housing (12) [Column 3, lines 26-30]. Housing (12) has a window (14). Within the housing (12) is a debulking assembly, rotatable cutter (31) [Column 3, lines 11-13].

In Simpson's catheter, the junction of the flexible body (36) and rigid housing (12) *will be rotatable*, i.e. bendable or flexible. The flexible body has been made flexible so that it can bend and twist through the tortuous vascular system, en route to the arterial artery [Column 3, lines 30-41], and therefore the point just proximally adjacent to the junction of the body (36) and housing (12) will also be flexible [see Attachment #1]. A deflection at this *joint* [see Attachment #1] will cause the axis of the housing (12) to be at an oblique angle relative to the flexible body (36). Thus, when the drive shaft (37) is extended distally, it will push the cutter (31) straight forward, and often, the cutter will be exposed through the window (14), as illustrated in Attachment #1. Further regarding Claims 14 and 15, the same cutter would be exposed, if it were initially in the position shown in Figure 2D, and then retracted proximally to the position shown in Attachment #1.

In one embodiment of his invention, Simpson shows guidewire (61) extending through cutter (31). This guidewire may slightly prevent cutter (31) from deflecting out of the window, but guidewires are generally quite flimsy and not necessarily

suited for such a purpose. Simpson, in another embodiment shows the guidewire (118) *not inserted through cutter (31)* [see Fig. 3]. In this embodiment there is nothing preventing the cutter from being exposed outside of the rigid housing (12) [Column 7, lines 30-45], when housing (12) is deflected relative to the flexible body (36), as shown in Attachment #1.

U.S. Patent No. 5,643,296 to Hundertmark et al. teaches the above scenario explicitly, *adding weight* to Examiner's opinion. Hundertmark names Patent Number 4,979,951 to Simpson specifically (column 2, lines 16-18), and in column 2, lines 28-30, says that such a device does "not securely hold the cutting blade within the housing." The family of Hundertmark is citing are atherectomy catheters having flexible proximal parts and hard distal housings, similar to Applicant's. In fact, the whole purpose of Hundertmark's invention is to solve the problem (cutter extending out of the housing) in the prior art by forming a guiding structure to maintain the cutter within the distal housing [Column 1—Column 2].

11. Regarding Claims 3 and 18, Simpson discloses the claimed invention, including a drive shaft (37) attachable to a driver for rotating the cutter (31) [Column 1, lines 40-49; Column 3, line 61 to Column 4 line 19].
12. Regarding Claim 4, Simpson's housing deflects towards the bottom of the page, and the window is facing towards the top, in the illustration of Attachment #1.
13. Regarding Claims 6 and 23, Simpson discloses a ramp (17) on the rigid housing opposite of the window [see Fig. 1A]. The ramp is *capable of* deflecting the debulking assembly further out of the window.

14. Regarding Claim 7, Simpson discloses a tissue debulking assembly moveable from a second position [Fig. 2C] to a first position [Fig. 2D]. When the tissue debulking assembly (31) is in the first position, the cutter (31) and drive shaft (37) block the window, separating the inner lumen of the device from the outside of the device.
15. Regarding Claim 8, when Simpson's debulking assembly is in the second position [Fig. 2C], the top of cutter (31) juts out above and beyond respective surfaces (16) and (18) of the window (13) [Fig. 2C].
16. Regarding Claim 10, Simpson's debulking assembly (31) is capable of performing the claimed intended use.
17. Regarding Claim 16, Simpson's cutter, while in the second position (the position shown in Attachment #1) extends beyond the outer diameter of the distal part of the body.
18. Regarding Claim 19, Simpson discloses single "control means 46" that drives the drive shaft (41), rotating it and extending it longitudinally [Column 3, lines 61-66].
19. Regarding Claims 20, 54, and 55, Simpson discloses a distal tip (26), used for the collection of an atheroma [Column 6, lines 9-20; progression from Fig. 2C to Fig. 2D]. Figure 2D shows the device packing the material into the collection chamber (26).
20. Regarding Claim 21, Simpson discloses a distal tip (26) [Column 2, lines 61-67], with a lumen for receiving guidewire (61) [see Fig. 1A]. Simpson discloses a second lumen (77) configured to receive a guide wire [Column 4, lines 42-45].

21. Regarding Claim 22, Figure 2D shows a third position, distal of the first two positions, which urges material into the collection chamber (26).
22. Regarding Claims 49, 50, 56-58, and 62, Simpson discloses a method according to the claimed invention. Simpson discloses moving the debulking device (31) from a first position [see Fig. 2B], in which it is within rigid housing (12), to an exposed second position, half way between the instances shown in Figures 2C and 2D. Simpson discloses deflecting the distal portion against the inner wall of an artery to position the debulking device in a desired position. The distal portion (12) will naturally deflect, relative to the flexible proximal portion (14), as the catheter system is threaded through the tortuous path of the arteries. Simpson recognizes this, saying that the rigid housing (12), which contains debulking device (31), and the proximal portion (14) can “*follow different curves* in the blood vessels and tortuous segments of blood vessels” [Column 3, lines 30-38]. Thus, regarding Claim 50, the central axis of the proximal portion will often vary from the central axis of the distal portion. Simpson further discloses passing the device through/past the material (93) to debulk the body lumen (92), as shown in the progression of Figures 2A—2E.
23. Regarding Claim 51, in use, as recognized by Hundertmark et al. (and explained above), because of the deflection between the distal and proximal portions, the debulking device (31) veers out of the path of the housing (12).
24. Regarding Claim 53, Figure 2C shows the material (93), and Figure 2D shows the hatched material having been cut off.

25. Claims 39, 41, and 44-48 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,911,734 to Tsugita et al. Regarding Claims 39 and 48, Tsugita discloses a method of removing material (debris within the blood) from a body lumen, including delivering a catheter system to a target site in the body lumen. Distal portion [struts (54)] are deflected radially, relative to the proximal portion (32) of the catheter system to expose the tissue debulking device, "filter mesh" (60) [Fig. 5A-5C; Column 8, lines 34-50]. A tissue debulking device is considered to be any device that removes material/debris/plaque/etc...from the body. The tissue debulking device (60) of the present invention catches particles floating in blood and removes them from the body [Column 8, lines 51-57]. The distal end (struts 54) of the device is shown deflecting, as one looks at the progression from Figure 5A to Figure 5C [Column 11, line 55 to Column 12, line 9]. The debulking device (60) moves from the first position shown in Figure 5A to a second position shown in Figure 5C.
26. Regarding Claim 41, Tsugita discloses sliding the tissue debulking device against a cam surface, distal end of component 40. In Figure 5A, the debulking device (60) is shown touching the end of cam surface (40), and in Figure 5B, the debulking device (60) has slid off of the surface.
27. Regarding Claim 44, Tsugita indirectly discloses packing material into a collection chamber [inside surface of debulking device (60)]. Debulking device (60) is meant to be a filter, catching debris material, but allowing blood to pass through it [Column 8, lines 51-57]. After the stent is inserted into the artery, and the debulking device has captured all the debris material caused by that insertion, the debulking

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device (60) is folded up, and pack/compress the material that has been collected therein [Column 12, lines 5-10].

28. Regarding Claim 45, Tsugita discloses urging the debulking device (60) outwards, as distal portions (54) expand outwardly. The debulking device (60) is said to engage the inner walls of the blood vessel [Column 12, lines 2-5], where it collects material from the body lumen.
29. Regarding Claim 46, Tsugita discloses attaching a guidewire (40) to a monorail delivery assembly on the catheter. The delivery assembly [Fig. 5A] has only one central axis, or “rail”, as opposed to having two catheters side by side.
30. Regarding Claim 47, Tsugita’s target site is a stent. His debulking device (60) is meant to catch debris formed by the insertion of a stent at a site in a carotid artery [Column 1, lines 12-28].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

31. Claims 11-12 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,979,951 to Simpson in view of U.S. Patent No. 5,250,059 to Andreas et al. Simpson discloses a distal tip (26) made out of “stainless steel or plastic” [Column 2, lines 66-67], with a lumen for receiving guidewire (61) [see Fig.

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1A]. The distal tip is used for the collection of an atheroma [Column 6, lines 9-20; progression from Fig. 2C to Fig. 2D]. Simpson fails to explicitly disclose a flexible distal tip, as claimed.

However, Andreas discloses the use of a flexible and soft distal tip with a rigid housing. Andreas teaches using such a flexible, soft distal tip to avoid causing trauma to blood vessels, while the catheter is being advanced therein (prior art atherectomy catheters with hard distal tips can cause trauma to blood vessels during advancement) [Column 1, lines 59-63 and Column 2, lines 6-25]. Therefore, it would be obvious to one having ordinary skill in the art at the time of the invention to replace Simpson's tip with a soft, flexible tip, as taught by Andreas, in order to reduce damage done to the interior wall of an artery during the advancement of a catheter assembly including a rigid housing.

32. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,979,951 to Simpson in view of U.S. Patent No. 5,569,277 to Evans et al. Simpson discloses a rotatable cutter (31), as explained above. Evans teaches that there are many ways to ablate an atheroma, including both cutting and employing laser energy [Column 1, lines 20-43]. Cutting with a rotating blade and cutting with a laser are thus alternate and analogous ways of cutting something, and substituting one for the other is only of mere ordinary skill in the art.

Allowable Subject Matter

Claims 32-38 and 63-68 are allowed.

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Claims 40, 42, and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,154,724 to Andrews

U.S. Patent No. 5,643,296 to Hundertmark et al.

U.S. Patent No. 5,954,745 to Gertler et al.

U.S. Patent No. 6,638,233 to Corvi et al.

U.S. Patent No. 5,989,281 to Barbut et al.

U.S. Patent No. 5,217,474 to Zacca et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BCP
BCP

December 19, 2003

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER

